

REMARKS

Reconsideration is requested.

Claims 38-56 are pending.

The Examiner's allowance of claims 38, 50 and 53 is acknowledged, with appreciation. See, page 1 of the Office Action dated November 18, 2003 (Paper No. 17).

The Section 112, first paragraph, rejection of claim 48 is traversed. Reconsideration and withdrawal of the rejection are requested in view of the following comments as well as the attached.

The Examiner appears to have rejected claim 48 based on an assertion that the term "binding fragment thereof" was not adequately described in the specification in such a way as to reasonably convey to one skilled in the art that the applicants were in possession of the claimed invention at the time the application was filed. The Examiner is understood to believe that the written description fails to set forth specific binding fragments or a means to obtain them. Clarification is requested in the event the applicants have misunderstood the Examiner's position.

The Examiner is urged to appreciate that the term "binding fragment" is well known to those ordinarily skilled in the art to represent that part of an antibody, such as is recited in claim 48, that binds the target. Methods of identifying and reproducing binding fragments of antibodies are, and were at the time of the invention, routine and well known to those of ordinary skill in the art. This is evidenced by the attached general teachings that were, at the priority date

of the invention, available to the skilled person (copies of which are attached hereto):

- Tijssen "Laboratory techniques in biochemistry and molecular biology – practice and theory of enzyme immunoassays" 4<sup>th</sup> edition Elsevier Science Publishes 1987 p 117-121
- Nicholls PJ, Johnson VG, Blanford MD, and Andrew SM (1993) An improved method for generating single chain antibodies from hybridomas. J Immunol Methods 165 p 81
- Huston JS, McCartney J, Tai MS, Nottola-Hartshorn C, Jin D, Warren F, Keck P and Oppermann H (1993) Medical applications of single chain antibodies. Intern Rev Immunol 10 p 195

Such methods are, and would have been regularly practiced in laboratories conducting such work.

Given that identifying and producing binding fragments of antibodies are well known techniques, the person of ordinary skill in the art would, contrary to the Examiner's assertion, have appreciated that the applicants were in possession of the presently claimed invention, and from combining the information given in the specification with that of the common general knowledge in the field would be able to practice the invention. The applicants respectfully submit therefore that the specification provides an adequate written description of the claimed invention.

For completeness, the applicants submit that the Examiner's position is inconsistent with the general approach taken by the U.S. Patent Office when

granting other patent applications. For example, a selection of granted U.S. patents have been identified which contain claims to antibodies, or binding fragments thereof, but which do not in the written description appear to teach how to define or obtain binding fragments or any examples thereof. The following are examples of such cases:

- U.S. 6,671,527 "Optical sensor for in situ measurement of analytes";
- U.S. 6,649,351 "Method for detecting a plurality of analytes by mass spectrometry";
- U.S. 6,625,479 "Optical sensor for in situ measurement of analytes".

Copies of these patents are attached for the Examiner's convenience.

Withdrawal of the Section 112, first paragraph, rejection of claim 48 is requested.

The Section 112, second paragraph, rejection of claims 39-49, 51-52 and 54-56 stated in paragraph 5 on page 4 of Paper No. 17 is obviated by the above amendments. Withdrawal of the Section 112, second paragraph, rejection is requested.

Claim 45 has been amended in response to the Examiner's comments in paragraph 6 on page 4 of Paper No. 17. Claim 45 provides for the further embodiment wherein the original cultures are mixed culture. Claim 46 has been similarly amended to provide consistent language with amended claim 45. Claim 47 has been amended according to the Examiner's suggestion in paragraph 8 on page 5 of Paper No. 17. Finally, claim 48 has been amended in response to the

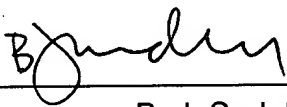
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Examiner's comments in paragraph 9 on page 5 of Paper No. 17 to provide adequate antecedent basis.

The claims as submitted should be in condition for allowance and a Notice to that effect is requested.

Respectfully submitted,

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